IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

GILEAD SCIENCES, INC.

Plaintiff,

v.

C.A. No. 22-cv-615-MN

LUPIN LTD., LAURUS LABS LIMITED, and CIPLA LIMITED,

Defendants.

CONSENT JUDGMENT AND ORDER

This action for patent infringement having been brought by Plaintiff Gilead Sciences, Inc. ("Gilead") against Defendant Cipla Limited ("Cipla") for infringement of U.S. Patent Nos. 9,708,342, 10,385,067, and 11,744,802 (the "Patents-in-Suit").

Gilead and Cipla (the "Parties") have agreed to terminate the pending litigation as it relates to Cipla's three-drug combination of bictegravir (50 mg), tenofovir alafenamide (25 mg), and emtricitabine (200 mg) for the treatment of HIV that is the subject of ANDA No. 216914 by the entry of this Judgment and Order; and

The Parties now consent to this Judgment and Order.

IT IS HEREBY ORDERED, ADJUDGED AND DECREED:

- 1. This Court has jurisdiction over the Parties and subject matter of this action.
- 2. All affirmative defenses, claims, and counterclaims in this action as they relate to the three-drug combination of bictegravir (50 mg), tenofovir alafenamide (25 mg), and emtricitabine (200 mg) for the treatment of HIV that is the subject of ANDA No. 216914 are hereby dismissed without prejudice.

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- 3. The claims of the Patents-in-Suit are valid and enforceable with respect to the manufacture, use, sale, offer for sale, and/or importation of the three-drug combination of bictegravir (50 mg), tenofovir alafenamide (25 mg), and emtricitabine (200 mg) for the treatment of HIV that is the subject of ANDA No. 216914 in the United States.
- 4. Except as agreed by and between the Parties, Cipla and its Affiliates are hereby enjoined from making, having made, using, having used, offering for sale, having offered for sale, selling, or having sold in the United States, or importing or having imported into the United States, the three-drug combination of bictegravir (50 mg), tenofovir alafenamide (25 mg), and emtricitabine (200 mg) for the treatment of HIV that is the subject of ANDA No. 216914 until the date agreed by and between the Parties. For the purposes of this Judgment and Order, "Affiliate" means, with respect to a Person, any other Person controlling, controlled by or under common control with such Person, but only as long as such control continues, where control and its correlates, as used in this definition, means (a) the ownership of at least fifty percent (50%) of the equity or beneficial interest of such other Person, (b) the right to vote for or appoint a majority of the board of directors or other governing body of such other Person, or (c) the power, whether pursuant to contract, ownership of securities, or otherwise, to direct the management and policies of such other Person.
 - 5. The Parties waive all right to appeal from this Judgment and Order.
- 6. This Court shall retain jurisdiction of this action and over the Parties for purposes of enforcement of the provisions of this Judgment and Order.

- 7. Each Party is to bear its own costs and attorneys' fees as they relate to the three-drug combination of bictegravir (50 mg), tenofovir alafenamide (25 mg), and emtricitabine (200 mg) for the treatment of HIV that is the subject of ANDA No. 216914.
- 8. Nothing herein shall be construed as preventing the U.S. Food & Drug Administration from granting final, effective approval to the three-drug combination of bictegravir (50 mg), tenofovir alafenamide (25 mg), and emtricitabine (200 mg) for the treatment of HIV that is the subject of Cipla's ANDA No. 216914.
- 9. Nothing herein applies to any product or application other than the three-drug combination of bictegravir (50 mg), tenofovir alafenamide (25 mg), and emtricitabine (200 mg) for the treatment of HIV that is the subject of Cipla's ANDA No. 216914.

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Attorneys for Defendant Cipla Limited

Attorneys for Plaintiff Gilead Sciences, Inc.

October 6, 2025

SO ORDERED this 6th day of October 2025.

The Honorable Maryellen Noreika

United States District Judge